PRELIMINARY AMENDMENT TO CLAIMS

We claim:

1. (currently amended) A ~~solid unit~~ dosage form comprising anhydrous mirtazapine or its pharmaceutically acceptable salts.

2. (currently amended) The dosage form as claimed in claim 1, wherein the dosage form comprises film-coated tablets of ~~mirtazapine, comprising~~ anhydrous mirtazapine or its pharmaceutically acceptable salts, low-substituted hydroxypropylcellulose and one or more pharmaceutically acceptable excipients.

3. (currently amended) The dosage form as claimed in claim 1, wherein the dosage form comprises ~~hard, compressed,~~ orally disintegrable tablets ~~dosage form~~ of ~~mirtazapine comprising~~ anhydrous mirtazapine or its pharmaceutically acceptable salts, and one or more non-effervescent excipients.

4. (currently amended) The dosage form ~~of anhydrous mirtazapine~~ as claimed in claim 2, wherein the particle size distribution of anhydrous mirtazapine or its pharmaceutically acceptable salt used in the tablet is such that the diameter ~~having a particle size distribution (PSD)~~ of 90% of the particles is less than 600 μm, more preferably ~~90% particles~~ less than 400 μm.

5. (currently amended) The dosage form ~~of anhydrous mirtazapine~~ as claimed in claim 3, wherein the particle size distribution of anhydrous mirtazapine or its pharmaceutically acceptable salt used in the tablet is such that the diameter ~~having a particle size distribution (PSD)~~ of 90% of the particles is less than 600 μm, more preferably ~~90% particles~~ less than 400 μm.

6. (original) A process for the preparation of film-coated tablets of mirtazapine, comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, low-

substituted hydroxypropylcellulose and one or more pharmaceutically acceptable excipients.

7. (original) A process for the preparation of hard, compressed, orally disintegrable tablet dosage form of mirtazapine comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, and one or more non-effervescent excipients.

8. (currently amended) The dosage form as claimed in claim 3, wherein the said non-effervescent excipients comprise binders, diluents, dispersing agents, ~~filler,~~ flavoring agents, sweetening agents, lubricants, glidants.

9 (currently amended) The dosage form as claimed in claim 3, further comprises anhydrous mirtazapine or its pharmaceutically acceptable salt from about 1 to 50% by weight of the tablet. ~~mixture of non-effervescent excipients comprising from about 10% to 80% of one or more diluents, at least one dispersing agent in the amount of 2% to 15%, from 0% to 15% of one or more binders~~.

10 (currently amended) The dosage form as claimed in claim 8, wherein the dispersing agent is selected from the group consisting of crosscarmellose sodium, crosspovidone, sodium starch glycolate, sodium carboxymethyl cellulose, hydroxypropyl cellulose, xanthan gum, alginic acid, alginates and carbopols ~~or~~ and combination thereof.

11 (currently amended) The dosage form as claimed in claim 8, wherein the diluent is selected from the group consisting of calcium phosphate-dibasic, cellulose-microcrystalline, cellulose powdered, calcium silicate, ploYols such as mannitol, sorbitol, xylitol, maltitol, sucrose, lactose and combinations thereof.

12 (currently amended) The dosage from as claimed in claim 8, where the binder is selected from the group consisting of methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, gelatin, gum Arabic, ethyl cellulose, polyvinyl alcohol, pullulan, starch, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, alginate, ~~and~~ plasdone and combinations thereof.

13 (currently amended) The dosage from as claimed in claim 8, wherein the lubricant is selected from the group consisting of talc, magnesium stearate, stearic acid, glyceryl behenate and mixtures thereof ~~preferably magnesium stearate~~ and ~~suitable~~ the glidants ~~is~~ selected from the group consisting of ~~includes~~ colloidal silicon dioxide, ~~and~~ talc and mixtures thereof.

14 (currently amended) The dosage form as claimed in claim 8, wherein the sweetener is selected from the group consisting of sugars ~~such as sucrose, lactose and glucose; saccharin and salts thereof;~~ , sucrose, lactose, glucose, saccharin, saccharin salts, mannitol, ~~and~~ aspartame and combinations thereof.

15 (currently amended) The dosage form as claimed in claim 8, wherein the flavoring agent is selected ~~form~~ from the group consisting of strawberry guarana, peppermint, cherry, mint, caramel, raspberry, lemon, orange, tuttifruity, banana, bubble gum, preferably strawberry, guarana, peppermint flavor or combination thereof.

16 (currently amended) The dosage form as claimed in claim 2, wherein the pharmaceutically acceptable excipients comprise binders, diluents, dispersing agents, ~~fillers,~~ lubricants and glidants.

17 (currently amended) The dosage form as claimed in claim 16, wherein the dispersing agent is selected from the group consisting of crosscarmellose sodium, crosspovidone, sodium starch glycolate, sodium carboxymethyl cellulose, hydroxypropyl cellulose, xanthan gum, alginic acid, alginates, ~~and~~ carbopols and mixtures thereof.

18 (currently amended) The dosage form as claimed in claim 16, wherein the diluent is selected from the group consisting of calcium phosphate-dibasic, cellulose-microcrystalline, cellulose powdered, calcium silicate, polyols, ~~such as~~ mannitol, sorbitol, xylitol, maltitol, sucrose and combinations thereof.

19 (currently amended) The dosage form as claimed in claim 16, wherein the binder is selected from the group consisting of methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol, pullulan, starch, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, alginate, ~~and~~ plasdone and mixtures thereof.

20 (Canceled)

21 (Canceled)

22 (new) A process for the preparation of film coated tablets of anhydrous mirtazapine or its pharmaceutically acceptable salts comprising the steps of:

i) blending anhydrous mirtazapine with disintegrants, diluents and/or binders
ii) milling and granulating the blend with purified water to obtain granules,
iii) drying the said granules and mixing the dried granules with diluents and lubricants,
iv) compressing the granule mixture into tablets,
v) coating the tablets.

23. (new) A process for the preparation of orally disintegrating tablets of anhydrous mirtazapine or its pharmaceutically acceptable salts comprising the steps of:

i) blending anhydrous mirtazapine with disintegrants, diluents and/or binders,
ii) milling and granulating the blend with a solvent to obtain granules,
iii) drying the said granules and mixing the dried granules with diluents, lubricants, flavoring agents, sweetening agents,
iv) compressing the granule mixture into tablets.